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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,819	06/12/2006	Dominique Bourel	065691-0408	3972

22428 7590 12/03/2008  
FOLEY AND LARDNER LLP  
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EXAMINER
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OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

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12/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,819	<b>Applicant(s)</b> BOUREL ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 48-98 is/are pending in the application.
- 4a) Of the above claim(s) 56,61-93 and 98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,48-55,57-60 and 94-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

1. Applicant's remarks filed on 09/05/2008 are acknowledged.

Claims 1 – 3 and 48 – 98 are pending.

Claims 64 – 93 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 05/21/2008.

2. Applicant's election of Species A (cell line YB2/0) in the reply filed on 09/05/2008 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that examination has been extended to include the Species of CHO cells.

Claims 56, 61 – 63, and 98 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected Species, there being no allowable generic or linking claim.

**Claims 1 – 3, 48 – 55, 57 – 60 and 94 – 97 are under consideration.**

3. Receipt is acknowledged of foreign priority papers (EPO Application 03290834.5) submitted under 35 U.S.C. 119(a)-(d), which papers are of record in the file of the instant application.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

5. Claim 95 is objected to under 37 CFR 1.75 as being a duplicate of claim 94. See MPEP § 706.03(k).

6. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

7. Claims 1 – 3, 48 – 55, 57 – 60 and 94 – 97 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 3, 48 – 55, 57 – 60 and 94 – 97 are indefinite in the recitation of antibodies or polypeptides which bind “only weakly” to the recited receptors. The term “weakly” is a relative term which renders the claim indefinite. The term is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree of binding. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

9. Claims 1 – 3 and 48 – 49 are rejected under **35 U.S.C. 102(b)** as being anticipated by Shields et al. (J. Biol. Chem., 2002, 277: 26733 – 26740; of record (IDS); see entire document).

Shields et al. teach a method of preparation of a human antibody by expressing a human IgG in a CHO-derived cell line, testing the binding of said antibodies to FcγRIIA, FcγRIIA and FcγRIIB, and selecting antibodies which bind to all three types of receptors (see entire document, in particular, e.g. the Results at pages 26734 – 26737, Table II, and Figures 2 – 5). The binding assays are performed using recombinant Fc receptors (e.g. Experimental Procedures at page 26734, second column). The antibodies are further selected by their ability to induce ADCC (e.g. Figure 6).

Therefore, the teachings of the reference anticipate the instant claimed invention.

10. Claims 52 – 55 and 96 are rejected under **35 U.S.C. 102(b)** as being anticipated by Shinkawa et al., (J. Biol. Chem., 2003, 278: 3466 – 3473; of record; see entire document).

Shinkawa et al. teach a method of producing antibodies in cell line YB2/0, a lymphoid cell line (see entire document, in particular e.g. the Results at pages 3468 – 3469). Shinkawa et al. teach that the antibodies thus produced have an increased ADCC (e.g. the Abstract), which is mediated by binding to FcγRIIIA (e.g. page 3472 second column, first full paragraph).

Although the reference is silent with regard to antibody binding to FcγRIIA and FcγRIIB, the reference teaches performing the same method steps using the same ingredients as instantly recited; therefore, the resulting antibodies inherently have the same properties as instantly recited. The recitation of immunomodulatory and cytotoxic antibodies in claims 53, 54 and 96 is not seen as differentiating the instant claims from the teachings of the prior art, because there is no manipulative difference between the claimed methods and those taught in the prior art.

Therefore, the teachings of the reference anticipate the instant claimed invention.

11. The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 50, 51, 94 and 95 are rejected under **35 U.S.C. 103(a)** as being obvious over Shields et al. (J. Biol. Chem., 2002, 277: 26733 – 26740; of record (IDS); see entire document).

The teachings of Shields et al. have been discussed above, and include a method of preparation of a human antibody by expressing a human IgG in a CHO-derived cell line, testing the binding of said antibodies to FcγRIIA, FcγRIIA and FcγRIIB, and selecting antibodies which bind to all three types of receptors (see entire document, in particular, e.g. the Results at pages 26734 – 26737, Table II, and Figures 2 – 5). The binding assays are performed using recombinant Fc receptors (e.g. Experimental Procedures at page 26734, second column). The antibodies are further selected by their ability to induce ADCC (e.g. Figure 6).

Shields et al. do not specifically exemplify calcium mobilization assay, cytokine secretion inhibition assay, or ADCC assays specific for individual subtypes of Fcγ receptors.

However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the above assays to antibodies produced by the method of Shields et al., because these assays were known and practiced in the art at

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the time. One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because these assays were known to be useful in antibody characterization, and have a reasonable expectation of success, because of the routine nature of the experimentation involved.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.



Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1 – 3, 48 – 55, 57 – 60 and 94 – 97 are provisionally rejected on the ground of nonstatutory obviousness-type **double patenting** as being unpatentable over claims 1 – 4 and 6 – 10 of copending Application 10,257,477; claim 19 of copending Application 11/517,525, and claim 33 of Application 10/527,664, published as US Pat. Pub. No. 2003/0175969, 2007/0009522, and 2006/0127392, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same or nearly the same methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1 – 3, 48 – 55, 57 – 60 and 94 – 97 are directed to an invention not patentably distinct from the claims of commonly assigned Applications listed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Applications, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

**16. Conclusion: no claim is allowed.**

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/

ILIA OUSPENSKI, Ph.D.

Primary Examiner

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November 30, 2008